Standard Operating Procedure

SUBJECT: Training Requirements for SOPs using Computer Based Training under the caBIG™ Program	SOP No.: AD-007
	Version No.: 1.0
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Standard Operating Procedure –

Training Requirements for SOPs using Computer Based Training

This cover sheet controls the layout and components of the entire document.

Issued Date: October 30, 2006

Effective Date: December 11, 2006

Department Approval:

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Peter Covitz

Chief Operating Officer, NCICB

QA Approval:

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George Komatsoulis

Director of Quality Assurance

Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

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Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	January 24, 2006	SOP WG Review	All pages	Document Creation
1.0	January 24, 2006	SOP WG Approval	All pages	Document Creation
1.0	February 20, 2006	BP SIG Approval	All pages	Document Creation
1.0	October 30, 2006	BP SIG/SOP WG	All pages	Initial release.

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1. Purpose

This SOP outlines the requirements for training on SOPs approved for use under the caBIG[TM] Program.

2. Scope

This SOP applies only to the Computer Based Training (CBT) developed for SOPs issued by the Best Practice SIG under the caBIG[TM] Program at the National Cancer Institute (NCI). Other job-related training is not covered under the scope of this SOP.

3. Requirements

3.1   The user must complete the CBT prior to utilizing effective SOPs.

3.2   Training must be performed with approved SOPs (Issued or Effective).

3.3   The CBT must be available for use on the Issued Date of the SOP.

3.4   There must be sufficient time between the Issued Date and Effective Date for SOPs in order to allow for training completion.

3.5   Participant sites are responsible for ensuring the appropriate personnel at their specific site are trained on the SOPs.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	AD-001	Develop and Maintain Standard Operating Procedures
4.2	N/A	21 CFR 820.25: Personnel Training

5. Roles & Responsibilities

Role	Responsibility
User	• Download and execute CBT prior to effective date of SOP (for new SOPs). • Download and execute CBT prior to utilizing any effective SOPs (new user).
NCICB	• Issue and publish SOPs. • Create and publish CBT for training on issued SOPs.

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Role	Responsibility
Study Coordinator	• Ensure site personnel have completed training specific to their role prior to providing role support of the activities of the clinical research trial.
Site Training Coordinator	• Ensure required personnel have completed SOP training. • Maintain training records.

6. **Attachments**	

This SOP will be used in conjunction with the following attachments listed below. These attachments must be used by all clinical trial management system adopters and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

TITLE	DESCRIPTION
1) Procedure Description for Training Requirements for SOPs	This document provides instructions for the use of the CBT to satisfy regulatory training requirements prior to the use of effective SOPs.
2) Process Flow for Training on SOPs	This document graphically depicts the work flow activities, by role, that are performed in the process for training on approved SOPs.